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MISCELLANEOUS

IN THE
Supreme Court of The United States

No. 72-555

October Term, 1972

CASPAR W. WEINBERGER, Secretary of Health, Education, and Welfare, and CHARLES C. EDWARDS, Commissioner of Food and Drugs, *Petitioners*

v.

BENTEX PHARMACEUTICALS, INC., ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

BRIEF FOR RESPONDENTS

OPINIONS BELOW, JURISDICTION, QUESTIONS PRESENTED AND STATUTES INVOLVED

The respondents adopt the petitioners' statements in regard to the foregoing.

STATEMENT

Certain matters have already been established by the briefs before the Court submitted in the companion cases of *Weinberger v. Hynson, Wescott and Dunning, Inc.*, No. 72-394; *Hynson, Wescott and Dunning, Inc. v. Weinberger*, No. 72-414 (Cross-petition); *CIBA Corporation v. Weinberger*, No. 72-

528; and *USV Pharmaceutical Corporation v. Weinberger*, No. 72-666.

The thorough and scholarly brief submitted in the *USV* case (No. 72-666) demonstrates, as was already conceded by the Food and Drug Administration, that heretofore the approval of a new drug application has been considered personal to the applicant (Petitioners' brief in such case, pgs. 32-51).

The clear distinction between the evidence relevant to approval of a new drug application and the evidence relevant to the determination of the applicability of the definition of a new drug has been emphasized in the *Hynson* brief (No. 72-414) at pages 25-28, and in the *CIBA* brief (No. 72-528) at page 10.

The implications of longstanding agency practice has been reviewed in the *CIBA* brief (No. 72-528) at pages 12 and 13, and in the USV brief (No. 72-666) at pages 32 and 38.

The preceding briefs have discussed the history of the Federal Food, Drug and Cosmetic Act. All have given their exposition of the plan of the Act.

The petitioners seek in some fashion to create a right of administrative adjudicatory determination as to whether a drug is "new" based upon the responsibility of the agency to pass on new drug applications under Section 505 of the Act. It will be shown in this brief that the approval, disapproval or withdrawal of approval of a new drug application, under Section 505 of the Act, has nothing to do with whether a drug is "new" or "old", and that to interject that question would violate the express provisions of Section 505.

When it is realized that Section 505 of the Act confers no jurisdiction on the Secretary to adjudicate the applicability of the "new drug" definition to any product, it then becomes obvious that the Secretary has no jurisdiction to make binding administrative adjudications of the "new", "old", or "grandfathered" status of any drug. There is, in the Act, no distinction between the enforcement powers given the Secretary as to the sale of an unapproved new drug, and the enforcement powers

created regarding any other prohibitions of the Act. Jurisdiction of all these issues is placed solely in the District Court by the express provisions of the Act.

Beyond the argument which follows the respondents, in preliminary statement, wish to make these points:

(1) It is no disgrace to be a "me-too" drug.

(2) The word "ineffective", as used by the Food and Drug Administration, does not mean what it seems to mean.

(3) The Courts have no need to fear increased litigation as a result of upholding the opinion of the court of appeals in this case.

(1)

Throughout the petitioners' brief there is the implication that a "me-too" product is somehow tainted.

If, during the period of 1938 to 1962, a drug had become generally recognized as safe, everyone had a right to produce it, if no patent existed. Such competition is desirable. It leads to lower prices for drugs. Drug prices were a major concern of the hearings held by Senator Kefauver in connection with the 1962 Amendments, and are still a major concern.

These competing products have the right to an independent life. They are not tied to the apron string of some one else's new drug application. The "pioneer' company may not have chosen to defend its product in hearings for withdrawal of its original new drug application. That application was completely personal to it and was not generic. Frequently such lack of defense indicates nothing more than that the revenue produced by the product in the hands of its original sponsor did not justify the expense of defending it.

Where the proponent of a competing product believes that it can prove that the product is not a "new" drug it is entitled to its own, independent right to do so.

(2)

Throughout the petitioners' brief is the word "ineffective". Generally this word means nothing more than that the

holder of an approved new drug application did not choose to submit evidence of effectiveness to the NAS/NRC review boards. The term does not imply that the drugs in question do not in fact have the effect claimed. The term only implies that evidence of effectiveness satisfactory to the review boards was not submitted for some reason.

The phrase "ineffective" thus generally refers to the failure of a particular applicant to meet or to attempt to meet a specific burden of proof with respect to its own product.

The use of the word "ineffective" must thus not be allowed to exercise the emotional impact carried by its lay meaning.

(3)

Throughout the petitioners' brief there is the repeated implication that a decision against its position will result in a flood of litigation.

The pharmaceutical industry is one of the great responsible American industries. Despite the presence of the Food and Drug Administration it is largely self-regulated and selfdisciplined. It is noteworthy how few cases have developed into serious litigation. Throughout the history of the Act there has been only a thin trickle of decided cases. Many of these cases involve fringe elements of the industry: food fads, strange curative machines, and cure-alls.

In normal course industry promptly and voluntarily discontinues sales of any product concerning which a question has been raised, and voluntarily recalls outstanding stocks. The inherent damage to the reputation of a firm arising from the publicity of a seizure, the desire to maintain friendly relations with the agency, the expense and risk of litigation, all contribute to make defense of a product a course of last resort. Honest recognition of the facts and the sense of public responsibility inherent in most members of industry, combined with the other considerations named, prohibit defense of an indefensible product.

The law as stated in the court below is, we submit, the law as it has always been understood by the industry and by

the agency in accordance with its longstanding practice. This Court's decision in affirmance will not add to the small volume of litigation.

ARGUMENT

INTRODUCTION AND SUMMARY

The provisions of Section 505 of the Act, pertaining to the approval, disapproval or withdrawal of approval of a new drug application, are directed solely to an application voluntarily filed "by any person" with the Food and Drug Administration.

The criteria for action upon such application are precisely defined by the Act. An application may neither be refused nor withdrawn because the agency regards it as unnecessary; nor may the directives of the Act as to when to refuse or to withdraw approval of an application be ignored by the agency on the ground that the drug so covered is no longer "new".

The Act defines circumstances which require approval of an application to be withdrawn despite general recognition of the safety and effectiveness of the product, when newly discovered and undisseminated adverse evidence becomes known to the agency.

The jurisdiction of the agency under Section 505 is not a "threshold question", nor is the agency called upon to determine its own jurisdiction. Its jurisdiction is created by the application. When that is filed the agency has jurisdiction of that application, filed by the applicant. Nothing in the language of Section 505 requires, allows or suggests that the agency is to decide, pursuant to its duties thereunder, whether a drug is "new".

The test of whether a drug is "new" is entirely different from the criteria of approval specified in Section 505.

The test of whether a drug is new has been recognized by many decisions to be its reputation among qualified experts, as is required by the definition provided by Congress in Section 201 (p) of the Act. The criteria of Section 505 are based on the extent of specific and concrete scientific

evidence in support of the drug submitted by the applicant, and relate to actual safety and effectiveness as shown by that evidence.

The criteria of Section 505 may be met in the absence of general recognition of the safety and effectiveness of a drug among the scientific community. Indeed, the Section was designed to allow marketing of newly developed products, which have not yet achieved such recognition. On the other hand, failure of an applicant to sumbit the required proof of safety and effectiveness under Section 505 (d) is no indication that such proof does not exist or that the drug is not generally recognized as safe and effective.

Congress deferred to the expertise of the agency in the evaluation of the scientific proof of the safety and efficacy of unknown products. It placed in the hands of the District Court, with the burden of proof upon the agency, the opinion issue of general recognition which determines whether a drug is "new".

During the thirty-four years of the existence of the Act few cases have been seriously litigated. Circumstances exist which discourage such litigation, in the absence of arbitrary action by the agency.

The innovations now sought by the agency as to its jurisdiction are more likely to cause delay, confusion and litigation than will continued, orderly enforcement under the law and practices heretofore existing.

I. THE TESTS OF WHETHER A DRUG IS "NEW" OR "GRANDFATHERED" ARE DISTINCT FROM THE CRITERIA ON WHICH ACTION ON A NEW DRUG APPLICATION IS BASED.

A. *The Courts have repeatedly recognized the distinction between scientific evidence of safety and effectiveness and the "general recognition" test embraced in the definition of a "new" drug under Section* 201 (p).

The distinction between the tests applicable to "new drug

definition" (201 [p]) and the criteria of Section 505 relating to approval, etc., of a new drug application has been treated in the cross petitioner's brief in the case of *Hynson, Westcott & Dunning, Inc. cross-petitioner v. Richardson, et al.*, No. 72-414, pp. 25-28, and at page 10 of the petitioner's brief in the case of *CIBA Corporation v. Richardson, et al.*, No. 72-528.

As is demonstrated by the argument in those briefs, with which the respondents concur, the application of Section 201 (p) to a drug requires only the determination of the consensus of competent medical opinion.

The evidence to support a new drug application is evidence provided by tests and results.

The statement by the petitioners in their brief, pages 55-57, that the issues are one and the same is an inadmissible repudiation of well established principles enunciated by the Federal courts.

> See e. g., *Merritt Corp. v. Folsom*, 165 F. Supp. 418 (D.D.C. 1958); *U. S. v.* 345 *Bulk Cartons . . . "Trim Reducing Aid Cigarettes"*, 178 F. Supp. 847 (D.N.J. 1959); *U. S. v. An Article of Drug . . . "Quinaglute,"* 268 F. Supp. 245 (E.D. Mo. 1967); *U. S. v. Articles of Drug . . . "Quick-O-Ver,"* 274 F. Supp. 443, 445-46 (D.Md. 1967); *U. S. v. An Article of Drug . . . "Line Away"*, 284 F. Supp. 107 (D.Del. 1968) affirmed other grounds 415 F. 2d 369 (3rd Cir. 1969); *U. S. v. 7 Cartons . . . "Ferro-Lac"*, 293 F. Supp. 660 (S.D. Ill. 1968) affirmed 424 F. 2d 1364 (7th Cir. 1970); *U. S. v. An Article of Drug . . . "Furestrol"*, 294 F. Supp. 1307 (D.Ga. 1969) affirmed 415 F. 2d 390 (5th Cir. 1969); *U. S. v. An Article of Drug . . . "Excedrin P. M."*, F. Supp. , CCH, Food Drug and Cosmetic Law Reporter, ¶ 40,486 (E.D.N.Y. 1971); *U. S. v. An Article of Drug . . . "Bentex Ulcerine," etc.*, F. Supp. , (D. Texas 1972), affirmed F.2d , CCH, Food Drug and Cosmetic Law Reporter ¶ 40,771 (5th Cir. 1972).

B. *Agency determination of the extent of general recognition is particularly subject to administrative bias, and industry needs the protection of the Courts.*

Where issues exist as to the application of Section 201 (p) to a drug an agency adjudication would be subject to bias, particularly unconscious bias.

The determination will rest upon the credence and weight to be given to conflicting expert testimony – not as to matters of fact but as to the existence or non-existence among the expert community of general recognition of the safety and effectiveness of a drug.

In determining questions of credence and weight as applying to the determination of a nebulous consensus, or lack thereof, the testimony of agency witnesses, or of witnesses already familiar to the hearing examiner would only by heroic effort on the part of the examiner be reviewed with truly judicial objectivity and perspective.

Errors arising from unconscious bias in giving weight and credibility to conflicting opinions are almost incapable of correction at the appellate level. If ever there were a case where the protection of the Federal judiciary is needed at the trial level, the "new drug" question is that case.

II. THE ISSUE OF WHETHER A DRUG IS "NEW" IS NOT MATERIAL TO THE APPROVAL, DISAPPROVAL OR WITHDRAWAL OF APPROVAL OF A NEW DRUG APPLICATION UNDER SECTION 505 OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT.

A(1). *The Act exactly specifies the information to be submitted, none of which relates to the question of whether the drug is "new".*

Section 505 (b) of the Act exactly specifies the information to be submitted as part of a new drug application. It states:

> "Such person shall submit to the Secretary as a part of the application

(1) full reports of investigations which have been made to show whether or not such drug is safe for use, and whether such drug is effective in use;

(2) a full list of the articles used as components of such drug;

(3) a full statement of the composition of such drug;

(4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;

(5) such samples of such drug and of the articles used as components thereof as the Secretary may require; and

(6) specimens of the labeling proposed to be used for such drug."

These provisions neither require nor suggest that evidence be submitted as to the general recognition of the safety and effectiveness of the drug among the scientific community ("new" drug definition, Section 201 (p) of the Act; J. A. 475). Nor do they require or suggest that evidence be submitted for determination of the "grandfathered" status of the drug. (Section 107 (c) of *Public Law*, 87-781, 76 Stat. 788-789: J.A. 481, 482).

The information required in the application is designed to allow determination of whether the application should be approved. It is not provided that an application may be used to secure an exemption from approval.

A(2). ***The Act exactly specifies the criteria on which approval or disapproval of the application shall be based, none of which relate to the question of whether the drug is "new".***

Section 505 (d) of the Act exactly specifies the criteria on which approval or disapproval shall be based.

It states:

(d) If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e), the term "substantial evidence" means evidence consisting of ade-

quate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labelling or proposed labeling thereof.

Provisions 1, 2, 3 and 4, quoted above, require the submission by the applicant of test results and of manufacturing methods.

Provisions 5, 6 and 7 permit the Secretary to *deny* the application based upon other information known to him, not furnished by the applicant, indicating that he should *not* approve the drug. The Secretary is not authorized under any of the provisions of Section 505 (d) to *approve* an application on any basis other than material furnished by the applicant. Only in the disapproval of an application may the Secretary take into account information from other sources.

No provision of 505 (d) authorizes the approval of a new drug application by the Secretary on the ground that the drug is not "new"; nor is there any provision authorizing disapproval of an application on such ground.

It is not material to the criteria prescribed for approval whether the drug is or is not a "new" drug.

A(3) *The Act exactly specifies the criteria on which withdrawal of approval shall be based; and these require, on the basis of new adverse information, withdrawal of approval of an application for a drug not regarded as "new".*

The Act exactly specifies the criteria for withdrawal of approval of a new drug application.

It states:

(e) The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw ap-

proval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with th evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or (4) that the application contains any untrue statement of a material fact:

None of the provisions of Section 505 (e) suggests that the Secretary may withdraw approval of an application on the ground that the drug is no longer "new". Nor do these provisions suggest that the Secretary may refrain from withdrawing approval if required to do so under the terms of the Section on the ground that the drug is no longer "new".

In fact, the withdrawal provisions contemplate that a drug already approved, and now generally recognized as safe and effective, may as the result of tests by new methods prove to be unsafe. The fact that unsuspected side effects may exist with respect to accepted products has long been emphasized by the agency.

Section 505 (e) does not suggest that the agency, in a withdrawal proceeding, may consider whether the drug is or is not still a "new" drug.

B. *The applicant is entitled to a ruling on its application, even though the FDA does not consider the drug as "new".*

(1) *The decision to file an application belongs to the applicant alone.*

The decision to apply for approval of a new drug application is up to the applicant. No procedure exists to compel him to do so, nor does procedure exist to deny him that right.

Attention was called in the petitioners' brief in *USV Pharmaceutical Corp. v. Weinberger, et al.* (No. 72-666) to a speech by Peter Barton Hutt, present Assistant General Counsel for the Food and Drug Administration. In that speech, presented at the Annual Convention of the Federal Bar Association, Miami, Florida, Sept 4, 1969, Mr. Hutt stated:

> 'The third, and final, general principle is that it is the primary and initial responsibility of the manufacturer of a product to determine the proper classification of his product, and to make certain that it meets all applicable legal requirements. It is in no instance necessary, and in most instances inadvisable, to ask the Food and Drug Administration for its opinion on the proper classification of the product. • • • It is • • • usually perferable for the manufacturer to exercise the obligation of proper classification given to him by the statute, rather than abdicating that responsibility to the Government.'

B(2) *No power is given the FDA to refuse an application on the ground that the drug is not "new".*

B(3) *Advisory opinions that a drug is not "new" may be and have been withdrawn.*

B(4) *Such advisory opinions are not binding nor are they protection against prosecution or other enforcement action initiated by third parties.*

No authority is vested in the Secretary to refuse a new drug application on the ground that it is not new.

There is now a regulation under which the agency offers advisory opinions as to whether drugs require a new drug application (36 FR 3372, J. A. 247-250). Such advisory opinions are not binding.

Prosecution or other enforcement proceedings by the agency, or by a United States Attorney, or derivatively by a consumer group (as in *American Public Health Association v. Veneman*, DDC, Civ. Action No. 1847-70, decided August 23, 1972) are not precluded by the existence of an advisory opinion. *Davis: Administrative Law Treatise* ¶4.09, Vol. 1, pages 265-267; *Nichols & Co. v. Secretary of Agriculture*, 131 F. 2d 651, 659; *SEC v. Torr*, 22 F. Supp. 602-612; *James Couzens*, 11 BTA 1040.

Advisory opinions may be and have been suddenly withdrawn. As admitted in petitioners' brief:

> "On May 28, 1968, the agency, by formal statement of policy premised on the need for full implementation of the NAS/NRC findings, revoked all opinions previously given to the effect that an article is 'no longer a new drug'."
>
> (Petitioners' brief, page 21)

Accordingly an applicant may have good reason to insist that the agency pass upon and approve its new drug application, even though there is an advisory opinion that none is required.

The applicant has an absolute right under Section 505 to submit its application for approval, and to obtain approval if the application meets the criteria of 505 (d).

The agency is given no authority to refuse an application nor to disapprove it on the ground that the drug is not "new".

The question of the "newness" of a drug is never before the agency for decision under Section 505. Its jurisdiction is invoked solely by the filing of an application, and by the

filing of that application the exercise of its jurisdiction is also commanded.

C. *The Drug Amendments Act of* 1962 *conferred no new jurisdiction on the FDA to determine the newness of a drug, but merely modified the new drug definition and the criteria for approval, disapproval or withdrawal of approval of a new drug application.*

The Drug Amendments Act of 1962, and the efficacy review conducted under contract with the NAS/NRC, have no relevancy at all to the question of the agency's jurisdiction to adjudicate, so as to bind any private person, the question of whether a drug is "new".

The 1962 amendment of Section 505 added the requirement that a new drug application be supported by "substantial evidence" of effectiveness. The jurisdiction of the agency to approve, disapprove or withdraw approval of a new drug application was unchanged. The efficacy requirement was simply added to the criteria for such action.

The 1962 Amendments, while adding to the labors of the Secretary, did not add to his jurisdiction under Section 505. That jurisdiction remained limited to the approval, disapproval or withdrawal of approval, upon exactly prescribed criteria, of new drug applications submitted to the agency.

D. *The restricted rights of appeal under Section* 505 *of the Act are additional evidence that the Secretary is not invested with jurisdiction by that Section to determine whether a drug is "new".*

The court of appeals did not hold, as asserted by the petitioners, "that the agency should not be held to have the power to adjudicate 'new drug' status because its determination would not be judicially reviewable."
(Petitioners' brief, page 47)

Instead it held that the absence of provision for appeal from a decision whether a drug is "new" strongly suggests the intended absence of the power to make that decision.

The court of appeals held:

> "It is not to be assumed that the Act confers an adjudicatory right on the Secretary from which no judicial review, however limited, is provided or allowed." (J. A. 268)

As authority for the absence of the right of appeal from a decision on the new drug issue when promulgated under Section 505 the court of appeals cited *Turkel v. FDA, et al.*, 334 F. 2d 844, and, more importantly, the express language of the Act.

In the *Turkel* case, *supra*, it was held that refusal by the Secretary to grant exemption from Section 505 under the investigative drug section (505 [i]) was not appealable.

At Section 505 (h) the Act provides:

> "An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section."

No authorization for appeal is provided from any other action by the Secretary which he may lawfully take under Section 505.

There is no appeal from the refusal of the Secretary under an imagined authority to exempt a product as "not a new drug". There is no provision for appeal from the refusal of the Secretary to withdraw approval of an application on the grounds that it is no longer necessary.

Unlike the specialized and technical judgment as to whether a new and unapproved product should be exempt for investigational use only, the question of whether a drug is "new" under Section 201 (p) has routinely been decided by the courts. The agency acknowledges that it may properly be so decided in enforcement proceedings (petitioners' brief, page 57, footnote 82).

The fact that an issue amenable to Court decision is unappealable when decided by the agency under Section 505 is persuasive evidence that Congress never intended to provide that the agency decide that issue.

E. *The lack of any procedure or regulations established by the agency to adjudicate whether a drug is "new" is evidence that no such jurisdiction has been assumed.*

The agency has never established regulations nor invited actions for an adjudication in hearings before it of the "new" or "old" status of a drug.

So far as respondents are aware such proceedings have never been instituted during the thirty-four years the Act has been in force.

So far as respondents are aware the agency has relied entirely on the District Court for adjudicatory enforcement against new drugs unlawfully marketed without approved applications.

The agency obviously is confused as to whether it should or could proceed under Section 505 or under the Administrative Procedure Act. As yet it has never faced the issue in a practical context.

The rendering of advisory opinions is not an adjudicatory proceeding.

The agency by longstanding practice has acted upon the premise that a disputed issue as to the "new" status of a drug must be resolved in the District Court. It has never after thirty-four years administratively undertaken an adjudicatory hearing of this issue. See *Davis: Administrative Law Treatise*, ¶ 5.06, Vol. 1, pp. 324-220, 1958.

> "Against the Treasury's prior longstanding and consistent administrative interpretation its more recent ad hoc contention as to how the statute should be construed cannot stand." *United States v. Leslie Salt Co.*, 350 US 383, 396.

F. *Section 505 of the Act bestows no jurisdiction on the FDA to adjudicate whether a drug is "new".*

(1) *The preceding analysis shows that this issue is not material to any proceeding under Section 505.*

There is no basis in Section 505 from which jurisdiction of the Sercretary may be inferred to determine the applicability of Section 201 (p) to a product.

The information required in a new drug application, the criteria for approval and for the withdrawal of approval, and the absence of expressly provided rights of appeal, all demonstrate that the issue of whether Section 201 (p) is or is not applicable is not to be decided by the Secretary under the jurisdiction granted by Section 505.

Equally persuasive is the fact that the applicant may not be refused the right to make its application. This is a valuable right which protects the applicant from the vagaries of official advice.

F(2) *If a new drug application is filed, the agency then has jurisdiction of such application. This jurisdiction does not depend on whether the drug is "new". No "threshold question" is raised for determination by the submission of an application.*

The petitioners' brief refers to the applicability of Section 201 (p) to a drug as a "threshold question" to be decided by it prior to acting upon a new drug application or withdrawing approval of an application.

"Threshold question" is an attractive and seductive phrase; but the applicability of Section 201 (p) to a product is a threshold over which the agency is neither urged nor invited by the provisions of Section 505. For the agency so much as to consider the applicability of 201 (p) when applying the provisions of 505 would be in patent derogation of its duties exactly prescribed by the detailed criteria of that Section.

The agency has no authority to deny an application on the ground that it does not consider the drug to be "new".

The agency has no authority to grant approval of an application on the premise that the drug is old or grandfathered, but must pass on the information submitted by the applicant. The applicant may point to well known, published studies conducted by others as part of his evidence, but the agency's decision must be based on that evidence – not on whether the product is generally recognized by qualified experts as safe and effective.

The agency has no authority to withraw approval of an application on the ground that it is no longer necessary, nor to decline to withdraw approval when adverse new material is discovered on the ground the product is already generally recognized as safe and effective.

The jurisdiction of the agency is created by the application itself, by nothing more and by nothing less. The application of 201 (p) to the product is irrelevant to that jurisdiction.

F(3) *The question of whether a drug is "new" is no different in its treatment under the Act from that of whether a food or drug is adulterated, misbranded, or otherwise sold under the prohibitions of the Act.*

The applicability of the new drug definition to a product, and the issue of whether an approval application must exist before that product may be lawfully marketed, stands simply on the same footing as the other prohibitions of the Act.

The prohibitions of the Act against the sale of misbranded and adulterated drugs, which define at great length when such conditions are deemed to exist (Sections 501 and 502), are fully as important in the policing of the industry as is the prohibition against sale of an unapproved new drug.

The prohibition against the sale of a misbranded drug is the basis upon which an ineffective grandfathered drug may be removed from the market.

The agency has never contended that it could administratively adjudicate a case of misbranding or adulteration. Yet nothing in the Act indicates that the agency's action against the sale of unapproved new drugs should proceed in a manner any different from its enforcement of the other important provisions of the Act. That enforcement is uniformly provided for by prosecutional action in a District Court (Sec. 302, 303 and 304). Jurisdiction is placed not in the agency but in the Court.

F(4) *The factual issues in an enforcement proceeding against a "new" drug unlawfully sold are generally simpler than those involved in a misbranding proceeding.*

The issue presented to a Court for decision as to whether a drug is "new" as that term is defined by Section 201 (p) is not a decision of a scientific fact (see Section 1 of argument, *supra*).

The issues of misbranding and adulteration are issues of scientific fact. The issue of whether a drug is "new" is, by contrast, an opinion issue only.

The question of whether in a misbranding proceeding a grandfathered drug is or is not effective in fact is thus more technical and complex than a "new" drug issue under 201 (p).

The Act makes no distinction between the jurisdictions of the agency and of the court based upon any special or unique character inherent in the issue of whether a drug is "new".

G. *Since the Food and Drug Administration has no jurisdiction to determine whether a drug is "new" it has no adjudicatory power under the Administrative Procedure Act to make such determination.*

The Administrative Procedure Act is available only when an agency has been invested with jurisdiction to decide the question at issue.

The Food and Drug Administration has no right to require industry to submit to *binding* adjudication in a proceeding before it, without specific legislative authorization to do so.

Prosecutorial enforcement of the prohibitions of the Act is directed to the jurisdiction of the District Court. Adjudicatory determination of whether a drug is "new" and sold in defiance of the prohibition of Section 301 (d), is not placed in the agency, nor is such adjudicatory determination provided as to adulteration or misbranding (301, a, b, c).

CONCLUSION

In summary this brief has demonstrated that whether a drug is "new", as defined by Section 201 (p) of the Act, is not material to the Secretary's responsibilities in approving, disapproving or withdrawing approval of a new drug application under the provisions of Section 505 of the Act. The question of whether a drug is "new" or "old" is of no concern to the Secretary under Section 505.

The jurisdiction of the Secretary under Section 505 of the Act is invoked simply by the filing of an application There is no "threshold question" for him to determine, nor may he divest himself of jurisdiction on the ground that the drug involved is no longer "new".

The Secretary's right to proceed against a "new" drug sold without an approved new drug application is no different from his right to proceed against adulterated food or mislabled "old" drugs.

His right is prosecutorial, not adjudicatory, and must be exercised by him in a proceeding in a District Court. Adjudicatory jurisdiction is vested in the District Court alone.

Therefore the decision of the Court of appeals for the Fourth Circuit should be affirmed.

Respectfully submitted.

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